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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/125,114 08/18/98 PRICE I P8129-8004

HM12/1013
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EXAMINER

BERMAN, A

ART UNIT

PAPER NUMBER

1615

7

DATE MAILED:

10/13/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/125,114

Applicant(s)

PRICE, IAN ASHLEY

Examiner

Alysia Berman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 01 September 1999.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 14) ☒ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 17) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other: _____.

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DETAILED ACTION

1. Receipt is acknowledged of the Amendment and Information Disclosure Statement filed 1 September 1999.

Allowable Subject Matter

2. The indicated allowability of claims 1-7, 10, 16-18, and 21-26 is withdrawn in view of the newly discovered reference(s) to Birrenbach et al. (US 5631296). Rejections based on the newly cited reference(s) follow. The examiner apologizes for mistakenly indicating the allowability of these claims.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 20-22 and 25 are rejected under 35 U.S.C. 102(e) as being anticipate by Geisslinger et al. (US 5565613).

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Geisslinger et al. teaches a compressed tablet comprising ibuprofen, fillers such as lactose, disintegrates (col. 1, lines 63-65), and a calcium compound such as calcium carbonate (col. 2, lines 47-48). See column 2, lines 12-14 for sodium salt of ibuprofen. Example 1 teaches dry mixing the ingredients and pressing the resultant mixture into tablets. Note that example 1 teaches ibuprofen and the carrier within the range instantly claimed. See column 2, lines 39-40 for racemic mixture.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-8, 10-13, 16-18, 20-22, and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geisslinger et al. in view of Gregory et al. (US 5262179) and further in view of Elger et al. (US 4844907).

Geisslinger et al. teaches all of the limitations of the claims as stated above. Geisslinger does not teach the crushing strength of the tablets, sodium carbonate or bicarbonate, the ratios instantly claimed, or a layered tablet. Geisslinger, however, does teach that the tablets have improved (col. 2, lines 35-37).

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Gregory et al. teaches powder compositions of the sodium salt of ibuprofen (col. 3, lines 26-27) with sodium bicarbonate (abstract) that may be formulated into tablets (col. 4, lines 3-6). See column 3, lines 55-57 for ratio of bicarbonate to ibuprofen salt and example 1 for ratio of carbonate to filler. The composition may further comprise conventional disintegrates and fillers (col. 4, lines 14-19). The ingredients are mixed together under dry conditions (example 1).

Elger et al. teaches *inter alia* ibuprofen in one layer of a layered tablet (abstract).

The weight percents, crushing strength, and ratios as instantly claimed are not considered critical to the invention absence evidence to the contrary. It is within the skill in the art to select optimal parameters to achieve a desired result. See *In re Boesch*, 205 USPQ 215, (CCPA 1980). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the sodium salt of ibuprofen with the sodium bicarbonate as taught by Gregory in the tablet of Geisslinger with the reasonable expectation of producing an ibuprofen salt tablet. The motivation lies in the art-recognized desire for an ibuprofen tablet that exhibits rapid dissolution.

7. Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geisslinger et al. in view of Birrenbach et al. (US 5631296) and further in view of Denton (WO 89/02266).

Geisslinger et al. teaches all of the limitations as stated above. Geisslinger does not teach the crushing strength of the tablet, the amount of carbonate and sodium salt of ibuprofen, the ratios instantly claimed, direct compression without pregranulation, or a layered tablet.

Birrenbach et al. teaches ibuprofen pellets comprising 0.1 to 10.0% by weight sodium carbonate, and 0.1 to 5% by weight microcrystalline cellulose or lactose (col. 3, lines 41-54). The pellets may be directly compressed into tablets (col. 4, lines 19-20). The tablets may further

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comprise crosscarmellose sodium and sodium starch glycolate (col. 5, lines 44-45) and have a disintegration time of less than 2 minutes (col. 5, lines 64-66). It is the examiner's opinion that a composition containing the same ingredients within the instantly claimed ranges would also be within the instantly claimed ratios. Birrenbach does not teach the crushing strength of the tablets, a salt of ibuprofen, mixing the ingredients under dry conditions, or a layered tablet.

Denton teaches granules of ibuprofen formed into tablets with a crushing strength of more than 5 kp and a disintegration rate of 5 minutes or less (page 7, lines 30-34). See also Table 4 on page 11. Denton does not teach an alkali metal carbonate or bicarbonate, a salt of ibuprofen, crosscarmellose sodium or sodium starch glycolate, or a layered tablet.

It is well known in the art, as shown by Elger et al. above, to make layered tablets containing ibuprofen. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Geisslinger with Birrenbach and Denton with the reasonable expectation of producing a compressed ibuprofen tablet. The motivation lies in the art-recognized desire for rapid release ibuprofen tablets with improved tableting properties.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alysia Berman whose telephone number is 703/308-4638. The examiner can normally be reached on 8:00-4:30, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703/308-2927. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703/305-3704 for regular communications and 703/305-3704 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-1234.

A handwritten signature in cursive script, appearing to read "Alysia Berman", followed by a long horizontal line extending to the right.

Alysia Berman
Patent Examiner
October 7, 1999

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600